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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,280	01/20/2004	Joanne Peart	02940086CA	6861

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,280	PEART ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25-48,50 and 52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 25-48, 50, 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 23, 25-48, 50, and 52-55 are pending. The receipt and consideration of Applicant's amended claims, arguments/remarks, and the declaration of Dr. Jeffry G. Weers filed under 37 C.F.R. 1.132, all submitted on April 4, 2006, is hereby acknowledged.

Specification

The objections of the specification for (a) the incorporation of foreign reference WO 01/03690 on page 18 of the disclosure and (b) minor informalities (see page 2 of the previous office action) **are withdrawn**, because said reference has been removed from the specification and the minor informality has been corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 24, 30-36, and 41-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 23, 26-28, 30-35, 37-44, 46-48, 50, and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) **is maintained**. Applicant has cancelled claims 24 and 51.

The rejection of claim 36 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 above, and further in view of *Workshop on the Medical Utility of Marijuana* (IDS: page 4, 2nd paragraph in the section entitled "Appetite Stimulation/Cachexia." National Institutes of Health, August 1997) **is maintained**.

The rejection of claims 25, 45, and 52 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 above, and further in view of Pars et al. (U.S. Patent No. 3,728,360) **is maintained**.

The rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51,

and 53-55 above, and further in view of Ohlsson, A. *et al.* (*Clin. Pharmacol. Ther. 28*, 409-416) **is maintained**. Applicant has cancelled claims 49 and 56.

The rejection of claims 43-48, 50, and 52-55 under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961) **is maintained**. Applicant has cancelled claim 51.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 26-29, 43, 44, 46, 48, 50, and 52-55 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005) **is maintained**. Applicant has cancelled claims 24, 49, and 56.

Response to Arguments

Applicant's arguments filed April 4, 2006 have been fully considered but they are not persuasive. The declaration of Dr. Jeffry G. Weers filed under 37 C.F.R. 1.132, submitted on April 4, 2006, has been considered, but was found unconvincing. Applicant's traversal of the prior art rejections under 35 U.S.C. § 103(a) and the declaration of Dr. Weers rely on the assertion that a person of ordinary skill in the art would not have been motivated at the time of Applicant's invention to utilize hydrofluoroalkane (HFA) propellants in an inhalable formulation comprising tetrahydrocannabinol (THC), because of the previous difficulties of formulating THC in chlorofluorocarbons (CFC) and the extremely low solubility of other hydrophobic art recognized active agents in HFA propellants. The Examiner respectfully disagrees. A person of ordinary skill in the art would have been motivated to prepare THC formulations utilizing HFA propellants instead of CFCs, because, as taught by McNally, CFCs were being phased out in favor of propellants, such as hydrofluorocarbons, which were known to be less harmful to the ozone layer. It is also noted that the McNally reference teaches a respirable fraction ranging from 45-69%, wherein the term "respirable fraction" is the percent by weight of particles having an aerodynamic particle size less than 4.7 microns. It is noted that the definition of respirable fraction in McNally lists "mm" as the unit of measurement, which the Examiner believes is a clear typographical error per what was well known in the art regarding respirable particle sizes (See, for example, Fig. 1 in Radhakrishnan et al. U.S. Patent No. 5,192,528). Furthermore, the advantages of inhalation administration and the necessity that inhaled active agent have particle sizes less than 5.8 microns for delivery to the deep lung, especially the alveoli, was well known

in the art at the time of the instant invention, (See, for example, Fig. 1 in Radhakrishnan et al. U.S. Patent No. 5,192,528; and Burns et al. U.S. Patent No. 5,284,133 col. 5, lines 29-46).

Regarding the amount of ethanol recited by Applicant, the prior art teaches an overlapping amount of ethanol ranging from about 3 to about 30% by weight, thereby obviating Applicant's recitation of ethanol in an amount up to about 15% by weight. Routine optimization of the amount of ethanol in inhalable formulations would have yielded the amount necessary to dissolve THC and adhere to federal regulatory restrictions on maximum ethanol content.

Conclusion

Claims 23, 25-48, 50, and 52-55 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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